

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Donnelly, John J. et al.Serial No. 10/664,391Filed: September 17, 2003For: SYNTHETIC HEPATITIS C GENESArt Unit: 1646

Examiner: _____

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

**INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR 1.97**

Sir:

1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application. This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention. In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).

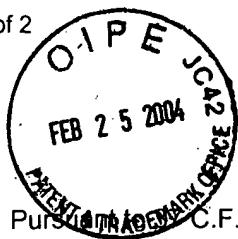
2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.

4. Pursuant to the waiver by the Office of the requirement under 37 CFR 1.98 (a)(2)(i) dated July 11, 2003, if the filing date of this application is after June 30, 2003, copies of each cited U.S. patent and each U.S. patent application publication are not enclosed herewith.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on the date appearing below.

MERCK & CO., INC.By Jode R Hobbs Date 2-23-04

**INFORMATION DISCLOSURE STATEMENT**

5. Pursuant to 37 C.F.R. 1.98(d), copies of references listed on the attached form that were submitted to or cited by the Office in a related application upon which the instant application relies for an earlier filing date under 35 U.S.C. 120 are not enclosed. Related application(s) in which references were submitted to or cited by the Office are as follows:

RELATED APPLICATION		
U. S. SERIAL NUMBER	FILING DATE	MERCK CASE
09/194,949	June 6, 1997	19732YP

If this is inconvenient, additional copies will be submitted upon request.

6. In accordance with 37 C.F.R. 1.97, (check one)

- ☐ the attached information is filed within three months of the filing date of the captioned case.
- ☒ the attached information is filed more than three months after the filing date but prior to the mailing of a first Office Action on the merits.
- ☐ the attached information is being filed more than three months after the filing date and after the mailing of a first Office Action on the merits, but before the mailing date of a Final Action or Notice of Allowance. The enclosed authorization is therefore given to charge Deposit Account No. 13-2755 for the fee required under 37 C.F.R. 1.17(p).
- ☐ the undersigned certifies that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement.
- ☐ the undersigned certifies that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated under 37 C.F.R. 1.56(c) more than three months prior to the filing of this Statement.

Respectfully submitted,



By: Sheldon O. Heber

Attorney _____ For Applicant(s)

Reg. No. 38,179

MERCK & CO., INC.

Patent Dept., RY60-30

P.O. Box 2000

Rahway, N.J. 07065-0907

(732)594-1958

Date: February 23, 2004

STATEMENT BY APPLICANT.

(use as many sheets as necessary)

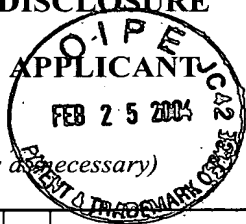
COMPLETE IF KNOWN

Application Number	10/664,391
Filing Date	September 17, 2003
First Named Inventor	Donnelly, John J. et al.
Group Art Unit	1646
Examiner Name	
Attorney Docket Number	19732YPCA

Sheet 1 of

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SignatureDate
Considered

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Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>			COMPLETE IF KNOWN		
			Application Number	10/664,391	
			Filing Date	September 17, 2003	
			First Named Inventor	Donnelly, John J. et al.	
			Group Art Unit	1646	
			Examiner Name		
Sheet	2	of	2	Attorney Docket Number	19732YPCA

NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
		Benvenisty, N. et al. "Direct introduction of genes into rats and expression of the genes", Proc. Natl. Acad. Sci. USA, 1986, Vol. 83, pp. 9551-9555
		Bukh, J. et al. "Sequence analysis of the core gene of 14 hepatitis C virus genotypes", Proc. Natl. Acad. Sci. USA, 1994, Vol. 91, pp. 8239-8243
		Chen, Z. et al. "Genetic Immunization of Mice with Plasmids Containing Hepatitis C Virus Core Protein-Encoding DNA", Vaccine Research, 1995, Vol. 4, pp. 135-144
		Farci, P. et al. "Lack of Protective Immunity Against Reinfection with Hepatitis C Virus", Science, 1992, Vol. 258, pp. 135-140
		Grantham, R. et al. "Codon catalog usage is a genome strategy modulated for gene expressivity", Nucleic Acids Research, 1981, Vol. 9, pp. R43-R74
		Honda, JP05069656A, Sequence Information, March 23, 1993
		Ide, Y. et al. "Characterization of the nuclear localization signal and subcellular distribution of hepatitis C virus nonstructural protein NS5A", Gene, 1996, Vol. 182, pp. 203-211
		Lagging, L. et al. "Immune Responses to Plasmid DNA Encoding the Hepatitis C Virus Core Protein", Journal of Virology, 1995, Vol. 69, pp. 5859-5863
		Lathe, R. "Synthetic Oligonucleotide Probes Deduced from Aminio Acid Sequence Data", Journal of Molecular Biology, 1985, Vol. 183, pp. 1-12
		Pachuk, C. et al. "HCV-Core DNA Vaccine Constructs Induce an Anti-HCV Core Immune Response", Molecular Approaches to the Control of Infectious Diseases, Cold Spring Laboratory, Cold Spring Harbor, NY, US, No. 95, 1995, pp. 123-127
		Ray, R. et al. "Hepatitis C Virus Core Protein: Role in Viral Persistence and Oncogenesis and the Development of a DNA Vaccine", International Business Communications, Inc., Chapter 5, 1997, pp. 53-58
		Selby, M. et al. "Expression, identification and subcellular localization of the proteins encoded by the hepatitis C viral genome", Journal of General Virology, 1993, Vol. 74, pp. 1103-1113
		Tokushige, K. et al. "Expression and Immune Response to Hepatitis C Virus DNA Vaccine Constructs", Hepatology, 1995, Vol. 22, pp. 220A
		Ulmer, J. et al. "Heterologous Protection Against Influenza by Injection of DNA Encoding a Viral Protein", Science, 1993, Vol. 259, pp. 1745-1749
		Zhu, N. et al. "Systemic Gene Expression After Intravenous DNA Delivery into Adult Mice", Science, 1993, Vol. 261, pp. 209-211

Examiner Signature		Date Considered	
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*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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